

192110

IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE
TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

FILED
NOV 15 AM 9:59
C. McLean
D.C.

STATE OF TENNESSEE, *ex rel.*
ROBERT E. COOPER, JR.,
ATTORNEY GENERAL and REPORTER,

Plaintiff,

v.

GLAXOSMITHKLINE LLC,

Defendant.

CASE NO. 12C4651

COMPLAINT FOR PERMANENT INJUNCTIVE AND OTHER RELIEF

1. Plaintiff, State of Tennessee, in its sovereign capacity, by and through Robert E. Cooper, Jr., the Tennessee Attorney General and Reporter ("Attorney General," "State of Tennessee" or "State"), at the request of Gary Cordell, Director of the Division of Consumer Affairs of the Tennessee Department of Commerce and Insurance ("Division") brings this action against Defendant GLAXOSMITHKLINE LLC for violating the Tennessee Consumer Protection Act ("TCPA"), Tenn. Code Ann. § 47-18-101 *et seq.*

2. The Attorney General brings this action pursuant to the TCPA, in the public interest, to protect the public's health, safety and welfare and pursuant to his general statutory and common law authority powers and duties. *See* Tenn. Code Ann. §§ 8-6-109, 47-18-108 and 47-18-114. The Attorney General and Director have reason to believe that the above-named Defendant has violated and/or is continuing to violate the TCPA. The Attorney General and Director also have reason to believe that this action is

in the public interest.

Upon information and belief, the State of Tennessee alleges as follows:

JURISDICTION AND VENUE

5. This Court has jurisdiction over Defendant pursuant to Tenn. Code Ann. §§ 47-18-108 and 47-18-114 because Defendant has transacted business within the State of Tennessee at all times relevant to this Complaint.

6. Venue for this action properly lies in Davidson County pursuant to Tenn. Code Ann. § 47-18-108(a)(3) because it is one of the counties in Tennessee where the alleged unfair and deceptive acts or practices took place and in which Defendant transacts or has transacted business at all times relevant to this Complaint.

7. Defendant waived 10 days' notice of intent to sue under Tenn. Code Ann. § 47-18-108(a)(2).

PARTIES

8. Plaintiff, State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General and Reporter, is charged with enforcing the TCPA, which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce. Pursuant to the TCPA, the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the TCPA and to secure such equitable and other relief as may be appropriate in each case. The Attorney General is authorized to seek a judgment which enjoins fraudulent or illegal business acts or practices, including but not limited to, any misrepresentation, concealment or suppression of a material fact, and which awards remedies, such as restitution, costs of administering restitution, attorneys' fees, civil penalties and any other appropriate relief for such acts. *See* Tenn. Code Ann. §

47-18-108.

9. Defendant GLAXOSMITHKLINE LLC is a Delaware corporation with a principal place of business at 1 Franklin Plaza, Philadelphia, Pennsylvania 19102. Defendant transacts business in Tennessee by promoting, selling, and distributing prescription drugs.

ALLEGATIONS RELATING TO DEFENDANT'S MARKETING OF AVANDIA

I. BACKGROUND INFORMATION

A. The Basic Medicine of Diabetes

11. Approximately 18.8 million people in the United States are diagnosed with diabetes.

12. Approximately 90-95% of adults diagnosed with diabetes have type 2 diabetes.

13. Type 2 diabetes results from the body's failure to produce enough insulin and/or the inability to use insulin properly.

14. Insulin is a hormone needed to convert sugar and other food into energy.

15. Without insulin, sugar builds up in the bloodstream that cannot be used by the cells; consequently, the cells are starved for energy causing numerous health problems.

16. Diabetes is a major cause of heart disease and stroke and is the seventh leading cause of death in the United States.

17. Since diabetics already have high cardiovascular risks, it is important that any treatment not increase these risks.

B. Treatment of Diabetes

18. The first line drug treatment for type 2 diabetes consists of established and inexpensive oral medications, including metformin and sulfonylureas.

19. Metformin is recognized as the "gold standard" in type 2 diabetes treatment. It reduces the amount of sugar released by the liver between meals, promotes weight loss, and reduces cholesterol and triglycerides levels. Metformin's side effects, which include nausea and upset stomach, are minimal.

20. Sulfonylureas are another popular first line treatment. They stimulate the pancreas to produce more insulin. Sulfonylureas combine well with other diabetes drugs for maximum effect on blood sugar. Their side effects include hypoglycemia (low blood sugar) and weight gain.

21. As diabetes progresses, patients typically need additional treatment agents and/or insulin therapy.

22. Rosiglitazone, which is sold under the brand name Avandia, is one of a newer generation of diabetes drugs called thiazolidinediones ("TZDs"). Avandia and other TZDs lower blood sugar levels by sensitizing the cells to use insulin more efficiently and effectively.

23. Avandia is available in three forms: Avandia tablets, Avandamet tablets, and Avandaryl tablets, which will all collectively be referred to as Avandia throughout this Complaint.

24. Avandamet tablets combine Avandia with metformin.

25. Avandaryl tablets combine Avandia with a sulfonylurea.

26. On May 25, 1999, the FDA approved Avandia for sale in the United States.

II. DEFENDANT'S MARKETING OF AVANDIA

27. Defendant promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile.

28. Defendant misrepresented that Avandia had a positive cholesterol profile when, in fact, Defendant did not possess competent and reliable scientific evidence to substantiate the claim.

29. Defendant also misrepresented that Avandia had cardiovascular benefits when, in fact, it does not, and may instead increase cardiovascular risks.

VIOLATIONS OF LAW: TENNESSEE CONSUMER PROTECTION ACT

30. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 29.

31. At all times relevant to this Complaint, Defendant engaged in "trade," "commerce," and/or a "consumer transaction" which constitutes the offering of or providing of "goods" and/or "services" as defined in Tenn. Code Ann. § 47-18-103 (5), (10), and (11) by engaging in the development, manufacture, promotion, marketing, sales, and interstate distribution of prescription drugs.

32. Defendant, in the course of engaging in the promotion, sales, and distribution of prescription drugs in Tennessee, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the TCPA, particularly Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27), by making written and oral representations about Avandia when Defendant knew the written and oral representations were not true.

33. Defendant, in the course of engaging in the promotion, sales, and

distribution of prescription drugs in Tennessee, has engaged in a course of trade or commerce which constitutes unfair, deceptive, or misleading practices, and is therefore unlawful under the TCPA, particularly Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(7), and (b)(27), by representing that Avandia had the benefit of reducing cardiovascular risks when, in fact, it does not and may instead increase cardiovascular risks.

34. Each and every unfair or deceptive act or practice engaged in by Defendant as recited above constitutes a separate violation of the TCPA as provided by Tenn. Code Ann. § 47-18-104(b).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General and Reporter, pursuant to the TCPA, the Attorney General's general statutory authority, the Attorney General's authority at common law, and this Court's equitable powers, respectfully requests that this Honorable Court enter an order:

A. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101, 47-18-108 and 47-18-116 and no court costs or litigation fees or costs of any sort be taxed against the State pursuant to Tenn. Code Ann. § 47-18-116;

B. That process issue and be served upon Defendant requiring Defendant to appear and answer this Complaint;

C. That this Court adjudge and decree that Defendant has engaged in the aforementioned acts or practices which violate the TCPA;

D. That, pursuant to Tenn. Code Ann. § 47-18-108(a)(1) and (a)(4), this Court permanently enjoin Defendant, its agents, employees, and all other persons and entities corporate or otherwise in active concert or participation with Defendant, from

engaging in the aforementioned unfair or deceptive acts or practices which violate the TCPA, and that such orders and injunctions be issued without bond pursuant to Tenn. Code Ann. § 47-18-108(a)(4);

E. That this Court order Defendant to pay civil penalties of \$1,000 for each and every violation of Tenn. Code Ann. § 47-18-108(b)(3);

F. That this Court enter judgment against Defendant and in favor of the State for the reasonable costs and expenses of the investigation and prosecution of Defendant's actions, including attorneys' fees, expert and other witness fees, as provided by Tenn. Code Ann. § 47-18-108(a)(5) and (b)(4);

G. That all costs in this case be taxed against Defendant pursuant to Tenn. Code Ann. § 47-18-116; and

H. That this Court grant Plaintiff such further relief as this Court deems just and proper.

Respectfully submitted,

FOR THE STATE OF TENNESSEE

I hereby certify that this is a true copy
of original instrument filed in my office
this 15 day of NOV 2012

RICHARD R. ROOKER Clerk

By A. [Signature]
Deputy Clerk

Robert E. Cooper, Jr.
ROBERT E. COOPER, JR.
Attorney General and Reporter
B.P.R. No. 10934

[Signature]
JENNIFER E. PEACOCK
Senior Counsel
B.P.R. No. 22227
Office of the Tennessee Attorney General
Consumer Advocate and Protection Division
P.O. Box 20207

Nashville, Tennessee 37202-0207
Telephone: (615) 532-5732
Fax: (615) 532-2910